K101982



## PREMARKET NOTIFICATION [510(k)] SUMMARY

DEC 2 1 2010

| | |
|---|---|
| Date Prepared: | July 13th, 2010 |
| Submitter: | St. Jude Medical, CRMD |
| Address: | 701 E. Evelyn Avenue<br>Sunnyvale, CA 94086 |
| Phone: | 408-522-6775 |
| Fax: | 408-522-6440 |
| Contact Person: | Gina Correa |
| Trade Name/Proprietary Name: | Merlin™ PSA Patient Cable EX 3150<br>Merlin™ PSA Cable Adapter EX3170<br>Merlin™ PSA "M" Adapter EX3180 |
| Common Name: | PSA Patient Cable and Adapters<br>Model Numbers: EX 3150, EX3170, EX3180 (Accessories) |
| Classification: | Class II, 21CFR870.3720 |
| Legally marketed device to which your firm is claiming equivalence: | Biotronik Patient Cable PK 67-L and the PA-4 Adapter (K022360 cleared on January 27, 2003) and St. Jude Medical PSA Cable Adapter Model Number 4053A (K093858 cleared on April 2, 2010) |

### INDICATIONS FOR USE/INTENDED USE

The Merlin PSA Patient Cable EX3150 is a three-channel resterilizable patient cable intended to connect the Merlin PSA to as many as three IS-1 leads or to SJ4 leads.

The Merlin PSA Patient Cable Adapter EX3170 is a three-channel adapter intended to connect the Merlin PSA to as many as three disposable patient cables. The EX3170 Cable Adapter can connect to the Models 4051/4051A disposable patient cables for IS-1 leads or to the Model 4161 disposable patient cable for SJ4 leads. The opposite ends of the disposable patient cables connect to implantable pacing leads.

The Merlin PSA "M" Adapter Model EX3180 is intended to connect the Merlin PSA to the two-channel Medtronic Model 2292 re-sterilizable patient cable. The opposite end of the Medtronic Model 2292 cable connects to implantable pacing leads.

Following use, the patient cables must either be disposed or re-sterilized, depending on the requirements of the cable.

## DEVICE DESCRIPTION:

**Merlin PSA EX3150 Patient Cable:**

The Merlin PSA Patient cable, Model EX3150 is an accessory to the Merlin PSA EX3100 system, which is intended to assess the pacing and sensing performance of the lead system prior to pulse generator implantation, or during invasive lead system troubleshooting.

The PSA Patient cable is intended to connect one to three implanted leads to the Merlin PSA EX3100, which is the patient interface part of the PSA product. The PSA Patient cable is the interface between the implanted leads and the PSA unit. The ODU connector end of the cable is connected to the Merlin PSA and the Alligator clip end is connected to the leads. The PSA Patient cable is re-sterilizable.

Please find below a schematic of the Merlin PSA Patient cable EX3150:

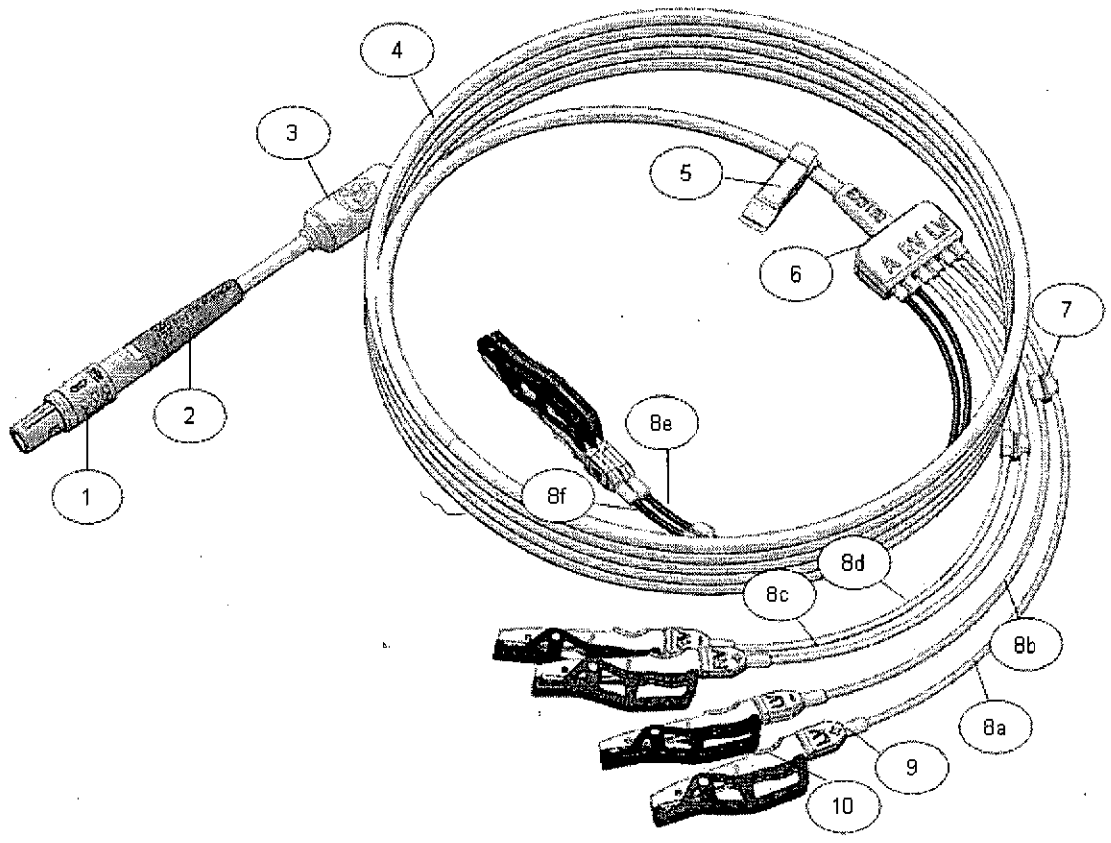



**Figure 1 :** Merlin PSA Patient Cable, Model EX3150

1. ODU connector, PSA-unit side
2. Connector bend relief, PSA-unit side

3. Ferrite
4. Cable – trunk part
5. Patient clip
6. Branching block
7. Anti-twist function (x3)
8. a) Lead wire LV+ (Left Ventricle)
   b) Lead wire LV- (Left Ventricle)
   c) Lead wire RV+ (Right Ventricle)
   d) Lead wire RV- (Right Ventricle)
   e) Lead wire A+ (Atrium)
   f) Lead wire A- (Atrium)
9. Alligator clip strain relief (x6)
10. Alligator clip, lead part (x6)

The PSA Patient cable, Model EX3150 is the interface between the implanted leads and the PSA unit. The patient cable is connected to the front panel of the Merlin PSA EX3100. Please find below a schematic of the Merlin PSA unit.

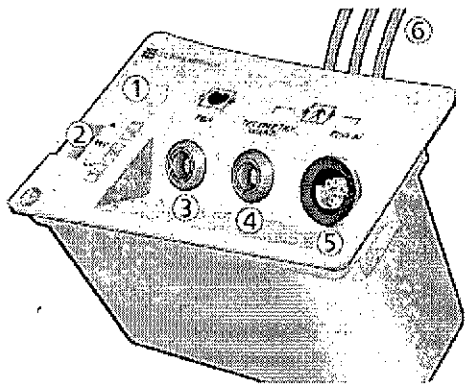



**Figure 2:** Merlin PSA, Pacemaker System Analyzer EX3100-Connector for patient cable or patient-cable adapter is identified as #3

The PSA Patient cable EX3150 is used during the implantation procedure to measure if the lead picks up signals from the heart accurately. It is connected to the lead by clamping the alligator clip to the connector pin of the lead.

**Technological Characteristics of the Merlin PSA Patient cable EX 3150 Compared to the Predicate Device:**

The Merlin PSA patient cable EX 3150 has similar intended uses, functionality and method of operation as the following predicate device.

- Biotronik Patient Cable PK 67-L and the PA-4 Adapter (K022360 cleared on January 27, 2003)

A brief summary of the SJM Merlin PSA cable EX3150 compared to the Predicate cable is provided below:

| | **Merlin PSA Patient Cable Model EX3150** | **Biotronik Patient Cable Model PK67-L + PA 4 adapter** |
|---|---|---|
| **Channels** | A, RV, LV | A, V |
| **Cable trunk material** | Silicone | Silicone |
| **Length** | 4.07 m | 2.64 m + 0.32 m PA 4 adapter |
| **Re-sterilization method** | Steam | Steam |
| **Clip design** | Non-dented Alligator clips | Alligator clips |
| **Compatible lead connectors** | IS-1, SJ-4 | IS-1 |
| **Touch proof lead connectors/ alligator clips** | Yes | No |
| **Touch proof PSA connectors** | Yes | Yes |
| **Lead connection isolation** | Built-in clip isolation | Isolation caps |
| **Channel labeling** | Text and color | Text and color |
| **Polarity labeling** | Text and color | Text and color |
| **Anti-twist clip on distal cabling** | Yes | Yes |
| **Patient clip** | Yes | No |
| **Serial number** | Yes | No |

**Merlin PSA EX3170 and EX3180 Patient Cable Adapters:**

Patient Cable Adapters - Merlin PSA Cable Adapter EX 3170, Merlin PSA "M" Adapter EX 3180 connects the Merlin PSA to commonly used PSA patient cables

Merlin PSA Cable Adapter EX3170 connects to the currently marketed disposable surgical cables 4051/4051A and 4161.

Please find below a schematic of the Merlin PSA cable adapter EX3170:

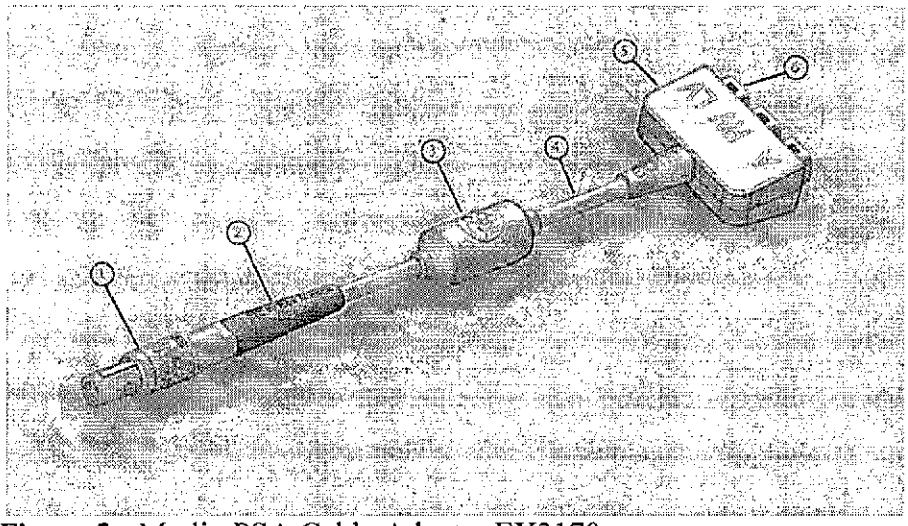


**Figure 3 :** Merlin PSA Cable Adapter EX3170

1. ODU connector, connects to the Merlin PSA EX3100
2. Connector bend relief
3. Ferrite
4. Cable
5. Branching block
6. Hypertronics connector (x3)

Merlin PSA "M" Adapter EX3180 connects to the Medtronic™ Model 2292 patient cable.

Please find below a schematic of the Merlin PSA cable adapter EX3180:

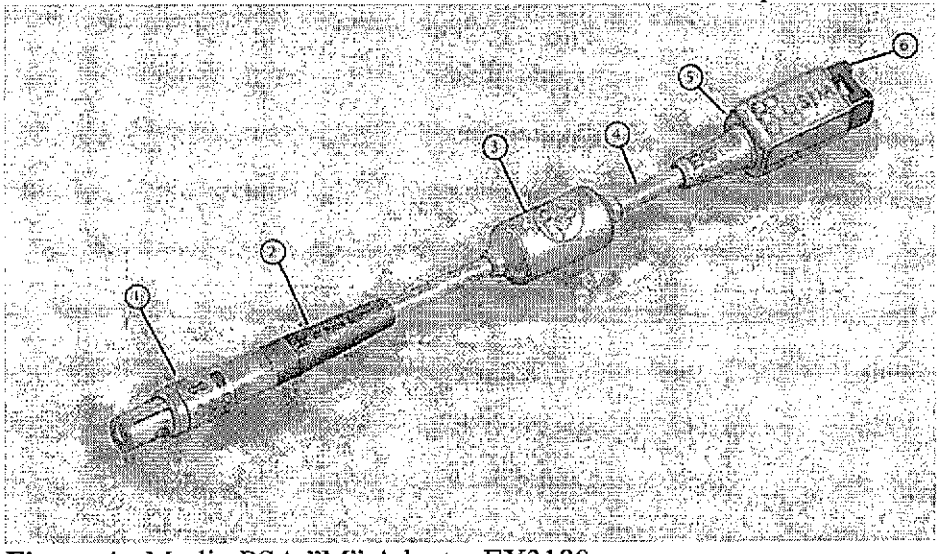


**Figure 4 :** Merlin PSA "M" Adapter EX3180

1. ODU connector, connects to the Merlin PSA EX3100
2. Connector bend relief
3. Ferrite
4. Cable

5. Connector block
6. Hypertronics connector

**Technological Characteristics of the Merlin PSA patient cable adapters EX 3170 and EX 3180 compared to the Predicate Device:**
The Merlin PSA patient cable adapters EX 3170 and EX3180 have similar intended uses, functionality and method of operation as the following predicate device.

- St. Jude Medical Model 4053A Patient Cable adapter (K093858 cleared on April 2nd 2010).

A brief summary of the SJM Merlin PSA cable adapters EX 3170 and EX3180 compared to the Predicate cable adapter is provided below:

| | **4053A** | **EX3170** | **EX3180** |
|---|---|---|---|
| PSA compatibility | SJM: 3150 & EX3100 2-channels | SJM: EX3100 3-channels | SJM: EX3100 2-channels |
| PSA Connector | Touch Proof Plastic Connector with snap on function and mechanical keying | Touch Proof Plastic Connector with snap on function and mechanical keying | Touch Proof Plastic Connector with snap on function and mechanical keying |
| PSA Connector Bend Relief | Pre-molded Polyurethane Elastomer | Molded Santoprene | Molded Santoprene |
| Raw Cable | PTFE insulated wires, wires twisted in pairs inside a braided shield, Outer Jacket in Santoprene | PTFE insulated wires, wires twisted in pairs inside a braided shield, Outer Jacket in Santoprene | PTFE insulated wires, wires twisted in pairs inside a braided shield, Outer Jacket in Santoprene |
| Ferrite | Ferrite over molded with Santoprene | Ferrite over molded with Santoprene | Ferrite over molded with Santoprene |
| Connector Block Bend Relief | Molded Santoprene | Molded Santoprene | Molded Santoprene |
| Connector Block | Connectors over molded with Santoprene with clear marking of channels and branding | Connectors over molded with Santoprene with clear marking of channels and branding | Connectors over molded with Santoprene with clear marking of branding |
| Patient Cable Connector | Hypertronics | Hypertronics | Hypertronics |
| Patient Cable type to be connected | 2 pairs of 4051/4051A or 4161 sterile Patient Cables | 3 pairs of 4051/4051A or 4161 sterile Patient Cables | 1 sterile 2292 Patient Cable |

**Summary of Studies:**

Verification and validation activities necessary to ensure that the SJM Merlin PSA Patient Cable's and adapter's product and system requirements were fulfilled have been successfully performed.

Product verification is documented in the following reports:

| | |
|---|---|
| Appendix 5.1 | Patient Cable EX3150 Design Verification Test Report |
| Appendix 5.2 | Patient Cable EX3150 Flexibility Verification Test Report |
| Appendix 5.3 | Patient Cable EX3150 Material and Biocompatibility Verification Report |
| Appendix 5.4 | Patient Cable EX3150 Shipping and Packaging Test Report |
| Appendix 5.5 | Patient Cable EX3150 Shelf life Aging Verification Report |
| Appendix 5.6 | Patient Cable EX3150 Cleaning and Sterilization efficiency verification for re-usable cables report |
| Appendix 5.7 | Patient Cable EX3150 Aging for re-usable cables Verification Report |
| Appendix 5.8 | Patient Cable EX3150 Sterilization Process Validation Report |
| Appendix 5.9 | Adapter EX3170 Verification Test Report |
| Appendix 5.10 | Adapter EX3180 Verification Test Report |
| Appendix 5.11 | Adapter EX3170/80 Shipping and Packaging Test Report |
| Appendix 5.12 | PSA System Verification Report |

**Biocompatibility:**

Material and Biocompatibility testing was performed on the Merlin PSA Patient Cable EX3150. All units tested passed the acceptance criteria. The report is provided in Appendix 5.3.

By design, the Merlin PSA Cable Adapter EX 3170 and the Merlin PSA "M" Adapter EX 3180 does not make blood tissue contact; hence no biocompatibility testing is required.

**Packaging and Shelf life:**

The PSA Patient cable EX3150 packaging configuration consists of a single Tyvek Sterile pouch providing the sterile barrier, which is packaged in a single Product box to protect the content. These are in turn packaged into a 20 Multipack box.

The tests that were conducted to demonstrate integrity and robustness of packaging and shelf life aging conditions for the Merlin PSA Cable EX3150 are reported in the Packaging/Shipping Test Report, see **Appendix 5.4.** and the Shelf life verification report, see **Appendix 5.5.**

Please refer to the figures below describing the various packaging configurations.

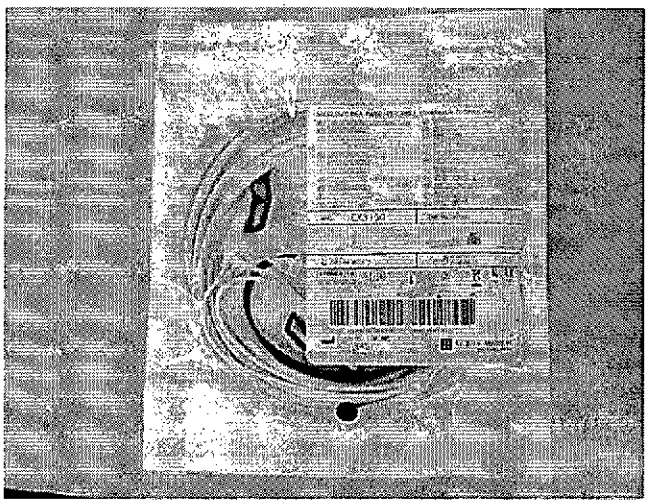


**Figure 5:** EX3150 Cable Assembly, including Tyvek® Pouch with Label

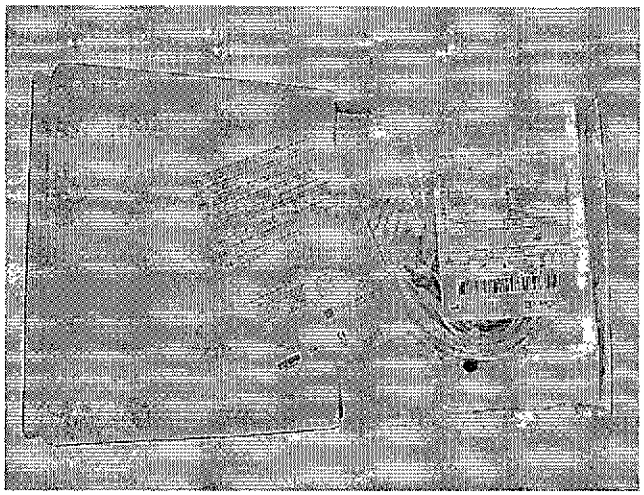


**Figure 6:** EX3150 Single Product Box with label, insert and Cable assembly and labeled Pouch placed inside.

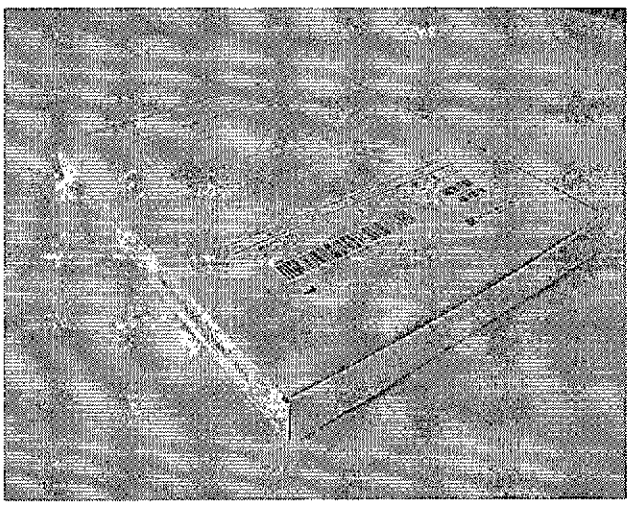


**Figure 7:** Single Product Box with Label

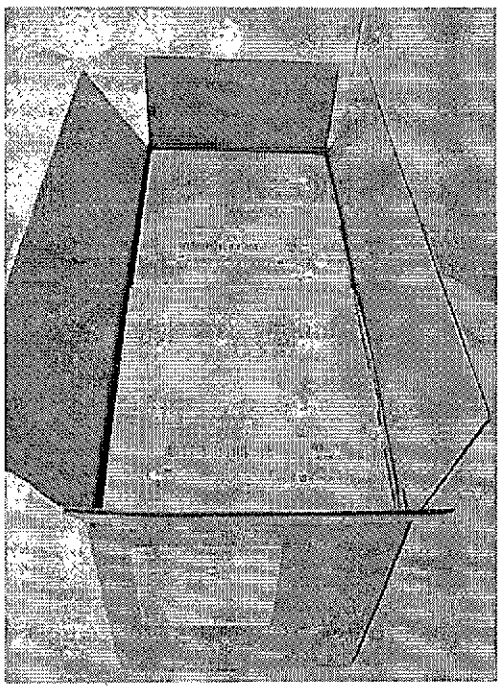


**Figure 8:** 20 Multipack Box

The Merlin PSA Cable Adapter EX3170 and Merlin PSA "M" Adapter EX3180 are packaged in a resealable bag. These are in turn packaged into a 50 Multipack box.
The test samples were packaged for standard shipment in accordance with our approved packing procedures and subjected to the ISTA 3A shipping test program for testing.

The tests that were conducted to demonstrate package integrity and robustness of shipping conditions for the Merlin PSA Cable Adapter EX3170 and Merlin PSA "M" Adapter EX3180. These tests were carried out and are reported in the Adapter EX3170/80 Shipping Test Report, see **Appendix 5.11.**

Merlin PSA Cable Adapter EX3170 and Merlin PSA "M" Adapter EX3180 are not supplied sterile and are not designed with any shelf life limiting components. Therefore shelf-life testing was not required. This is consistent with other market cleared SJM accessories.

Please refer to the figures below describing the various packaging configurations.

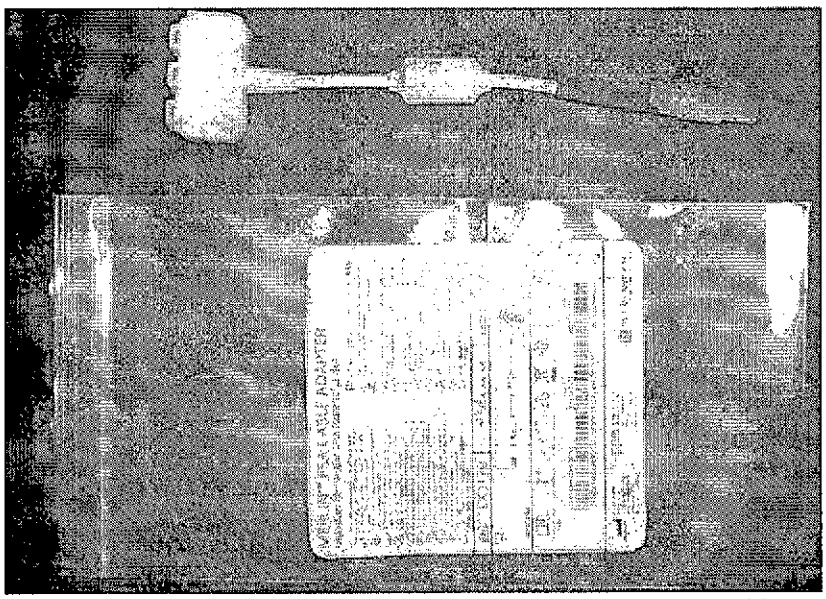


**Figure 9:** Merlin PSA Cable Adapter EX3170 is packaged in a resealable bag with packaging label

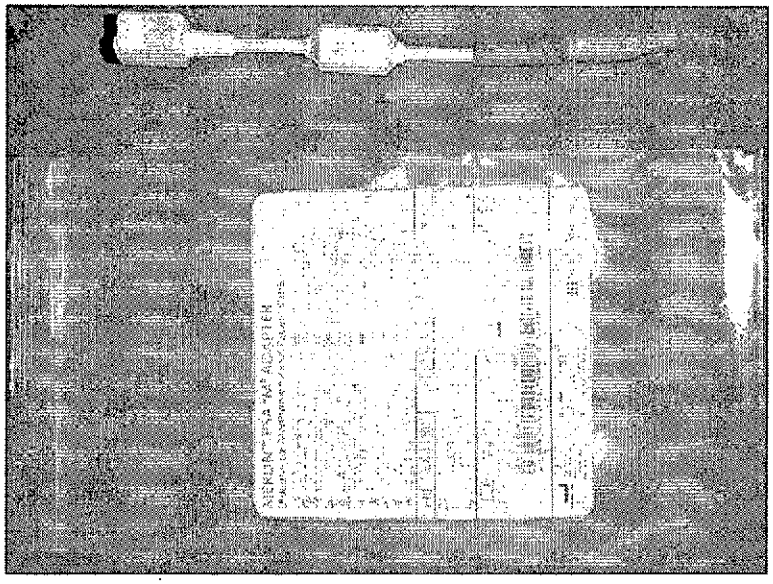


**Figure 10:** Merlin PSA "M" Adapter EX3180 is packaged in a resealable bag with packaging label

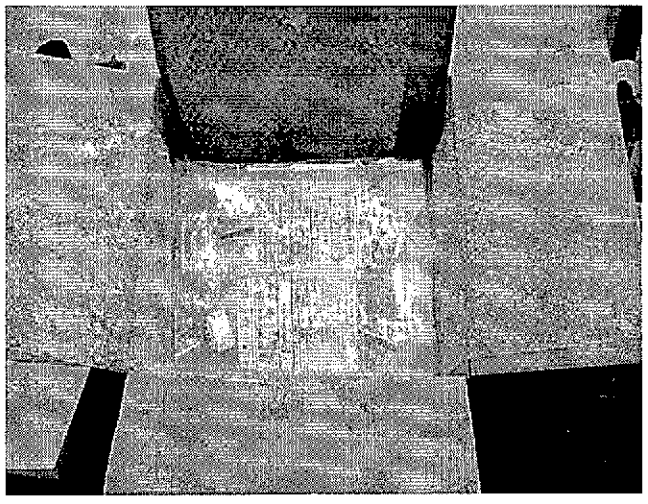


**Figure 11:** 50 Multipack Box

**Sterilization:**
The sterilization validation for the PSA Patient cable EX3150 was performed and reported in the Sterilization Process Validation report. See **Appendix 5.8**. The PSA Patient Cable is sterilized using 100% Ethylene Oxide prior to distribution. The sterility assurance level for the PSA Patient cable is verified to be $10^{-6}$.

Re-sterilization:
The Merlin PSA Patient cable EX3150 is intended for re-use in clinics. Verified methods for cleaning and re-sterilizing the PSA Patient Cable can be found in the Merlin PSA EX3100 Help Manual. See **Appendix 3.2**. The efficiency of the specified reprocessing methods has been documented in the Cleaning and Sterilization efficiency report. See **Appendix 5.6**. The integrity

of product performance has been documented in the Aging for Re-usable cables report. See **Appendix 5.7.**

Merlin PSA Cable Adapter EX3170 and Merlin PSA "M" Adapter EX3180 are not supplied sterile and are not intended to be used sterile. The materials used to manufacture the Merlin PSA EX3100 system are generic and do not specify a shelf life criteria. Therefore no shelf life is specified. This is consistent with other non-sterile SJM cable accessories.

**Conclusion:**

St. Jude Medical considers the SJM Merlin PSA Patient Cable EX3150 and the Merlin PSA patient cable adapters EX3170 and EX3180 to be substantially equivalent to the legally marketed predicate and referenced devices.

The results of the tests and compliance with applicable standards (reference Section 6) provide reasonable assurance that the SJM Merlin PSA Patient Cable and Adapters (EX 3150, EX3170 and EX3180) have been designed and tested to assure conformance to the requirements for its indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

St. Jude Medical, CRMD
c/o Ms. Gina Correa
701 E. Evelyn Avenue
Sunnyvale, CA 94086

DEC 2 1 2010

Re: K101982
Trade/Device Name:
Merlin™ PSA Patient Cable – EX3150
Merlin™ PSA Patient Cable Adapter - EX3170
Merlin™ PSA "M" Adapter-- EX3180
Regulation Number: 21 CFR 870.3720
Regulation Name: Pacemaker Electrode Function Tester
Regulatory Class: Class II (two)
Product Code: DTA
Dated: December 9, 2010
Received: December 10, 2010

Dear Ms. Correa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

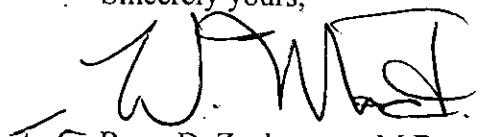
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K101982

Device Name: **Merlin™ PSA Patient Cable – EX3150**
**Merlin™ PSA Patient Cable Adapter - EX3170**
**Merlin™ PSA "M" Adapter EX3180**

DEC 2 1 2010

Indications for Use:

The Merlin PSA Patient Cable EX3150 is a three-channel resterilizable patient cable intended to connect the Merlin PSA to as many as three IS-1 leads or to SJ4 leads.

The Merlin PSA Patient Cable Adapter EX3170 is a three-channel adapter intended to connect the Merlin PSA to as many as three disposable patient cables. The EX3170 Cable Adapter can connect to the Models 4051/4051A disposable patient cables for IS-1 leads or to the Model 4161 disposable patient cable for SJ4 leads. The opposite ends of the disposable patient cables connect to implantable pacing leads.

The Merlin PSA "M" Adapter Model EX3180 is intended to connect the Merlin PSA to the two-channel Medtronic Model 2292 re-sterilizable patient cable. The opposite end of the Medtronic Model 2292 cable connects to implantable pacing leads.

Following use, the patient cables must either be disposed or re-sterilized, depending on the requirements of the cable.

| Prescription Use ___X___ (Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____ (21 CFR 801 Subpart C) |
|---|---|---|

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101982